

**REMARKS**

The Office Action mailed May 23, 2002 has been received and reviewed. After entry of the present Amendment, claims 1-24 are pending in the Application. Claims 4, 5, 14, 15, 18 and 19 have been amended. Claims 22-24 have been canceled.

It is respectfully submitted that no new matter has been added. Claims 4, 5 were amended to correct typographic errors. Claims 14, 15 and 18 were amended to correct dependency and provide proper antecedent basis. Claim 19 was amended as noted above.

Favorable reconsideration and withdrawal of the rejections of the claims is respectfully requested in light of the amendments and comments presented herein.

**Rejection of Claims under 35 U.S.C. § 112, First Paragraph**

In the Office Action, claim 22 is rejected for lack of enabling description in the specification. Claim 22 has been canceled. Thus, this rejection has been mooted.

**Rejection of Claims under 35 U.S.C. § 112, Second Paragraph**

In the Office Action, claim 18 is rejected for lack of antecedent basis for the term "the polyetherimide coating." Claim 18 now depends appropriately from claim 15. Claim 15 provides antecedent basis for "the polyetherimide coating."

Thus, it is respectfully asserted that the rejection is overcome by the present amendment and notification to that effect is earnestly solicited.

**Rejection of Claims under 35 U.S.C. § 102**

In the Office Action, claims 19 and 20 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,251,640 ("Osborne"). Claims 23 and 24 are rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,951,494 ("Wang"). Claims 1-12 and 16-18 are rejected under 35 U.S.C. § 102(a) as anticipated by PCT Application PCT/US01/18720 ("The Cordis Reference"). Each of these rejections is respectfully traversed.

### **Rejection of Claims 19 and 20 over Osborne**

Claims 19 and 20 are alleged to be anticipated under 35 U.S.C. §102(b) by “Osborne”). Claims 19 and 20, after amendment, require that the core wire comprise “multiple, randomly-disposed non-metallic fibers and a binder resin...” In contrast, Osborne discloses, for example as depicted in Figure 1, that the core wire includes a “set of fibers 12 which are arranged substantially parallel to the longitudinal axis...” See col. 2, lines 30-36 and lines 48-51. This disclosure of parallel, longitudinally-oriented core fibers clearly does not anticipate claims directed to randomly-disposed core fibers, as described in the present application. Thus, Osborne does not anticipate claims 19 and 20. FIG. 6 illustrates the subject matter upon which amended claim 19 now is focused.

In light of the above, it is respectfully submitted that claims 19 and 20 are not anticipated under §102(b) by Osborne. Withdrawal of that rejection is respectfully requested.

### **Rejection of Claims 23 and 24 over Wang**

Claims 23 and 24 have been canceled without prejudice to filing continuing applications.

In light of the above, it is respectfully submitted that the rejections of claims 23 and 24 has been mooted.

### **Rejection of Claims 1-12 and 16-18 over The Cordis Reference.**

It is respectfully asserted that the cited reference is not prior art under 35 U.S.C. § 102(a) by the Cordis Reference. The effective date of the Cordis Reference for the purposes of §102(a) is its international publication date, December 21, 2001. The present application was filed January 26, 2001, eleven months prior to the publication of the cited reference. Thus, the present application has an earlier effective filing date than the cited reference under §102(a). As is stated in the MPEP §706.02(a)(III):

“...For 35 U.S.C. 102(a) to apply, the reference must have a publication date earlier in time than the effective filing date of the application, and must not be applicant’s own work.”

In light of the above, it is respectfully submitted that claims 1-12 and 16-18 are not anticipated nor suggested by the Cordis Reference. Withdrawal of the rejection is respectfully requested.

**Rejection of Claims under 35 U.S.C. § 103(a)**

In the Office Action, claim 21 is rejected under 35 U.S.C. § 103(a) as obvious over primary reference U.S. Pat. No. 5,251,640 (“Osborne”) in view of secondary reference U.S. Pat. No. 5,919,044 (“Sicurelli”). Claim 13 is rejected under 35 U.S.C. § 103(a) as obvious over primary reference PCT Application PCT/US01/18720 (“Cordis Reference”) in view of secondary reference U.S. Pat. No. 6,042,588 (“Munsinger”). Claim 14 is rejected under 35 U.S.C. § 103(a) as obvious over primary reference Cordis Reference in view of secondary reference U.S. Pat. No. 5,769,796 (“Palermo”). Claim 15 is rejected under 35 U.S.C. § 103(a) as obvious over primary reference Cordis Reference. in view of secondary references Palermo and Munsinger. Each of these rejections is respectfully traversed.

**Rejection of Claim 21**

Claim 19, from which claim 21 depends, requires that the core wire comprise “multiple, helically-wound non-metallic fibers and a binder resin...” As discussed above, the primary reference, Osborne, does not mention randomly-disposed fibers of the core materials. Osborne teaches a core wire that includes a “set of fibers 12 which are arranged substantially parallel to the longitudinal axis...” See col. 2, lines 30-36 and lines 48-51. Thus, Osborne fails to teach all required elements of claim 21, which in addition to the elements of claim 19, also requires that the fibers comprise carbon and the binder resin comprise a vinyl ester.

As acknowledged in the Office Action, Osborne does not teach the use of a binder resin comprising vinyl ester. Although Sicurelli discloses “a dental post and core system that includes an inelastic flexible post of a bundle of fibers...held together in a resin such as...vinyl ester resin,” it fails to remedy the deficiencies of Osborne as applied to the instant claims.

First, it is at least questionable whether one of skill in the art of guide wires would be motivated to combine the cited references, as the field of dentistry is non-analogous. A reference is pertinent if it “logically would have commended itself to an inventor’s attention in considering his problem.” MPEP 2141.01(a). Clearly, there are many materials suitable for use in dentistry which would not be useful in the construction of guide wires and vice versa. One of skill in the art, in seeking to create a guide wire useful during MR diagnostic

and therapeutic procedures would search for materials that are kink-resistant, pushable, steerable and torque transmissive, as discussed in the present specification. In this regard, it is doubtful that references from the field of dentistry in general, and dental post and cores in particular, would be instructive.

Second, the combination of the references does not teach or suggest all of the claimed limitations. As discussed, the primary reference fails to teach a helical orientation of the core material. The secondary reference does not remedy this deficiency.

For at least these reasons, claim 21 is not obvious over the combination of Osborne and Sicurelli. Withdrawal of the rejection is respectfully requested.

### **Rejection of Claim 13**

Claim 13 stands rejected over the primary Cordis Reference in view of the Munsinger secondary reference. As is noted above, the primary Cordis Reference is not prior art, with respect to the present application under 102(a).

The secondary reference, Munsinger, fails to teach or suggest the deficiencies of the Cordis Reference.

The Office Action states that Munsinger teaches that it is known in the medical arts to use PEEK (the subject matter of claim 13) to construct guide catheters because the material is sturdy and inexpensive. However, a review of Munsinger reveals that it discloses no such thing. Taken as a whole, Munsinger teaches that COBRAID, a material used in the shafts of stent delivery catheters, can be replaced by PEEK. Munsinger does not suggest that PEEK would be useful for other intravascular applications or that it is an alternative material for other applications. In addition, Munsinger neither discloses nor suggests that COBRAID is a suitable core wire material for guide wires.

Thus for at least these reasons, withdrawal of this rejection is respectfully requested.

### **The Rejection of Claims 14 and 15**

Claim 14, as amended, requires that the core wire comprise one or more helically wound carbon fibers or PEEK and that the core wire is coated with PEBAK polyetherimide. Claim 15 requires that the core wire comprise PEEK and that the core wire is coated with

polyetherimide. The cited references, either alone or in combination, do not teach or suggest these elements.

As is noted above, the primary Cordis Reference is not prior art under 35 U.S.C. §102(a).

Munsinger does not cure the deficiencies of the Cordis Reference for the reasons discussed above *i.e.*, it does not teach or suggest the use of PEEK as a core wire material.

Palermo also does not cure the deficiencies of the Cordis or Munsinger references with regard to claims 14 and 15. The Office Action states that Palermo teaches “it is known in the medical arts to coat guide wire cores with PEBA<sup>X</sup> polyetherimide to lubricate the guide wire in order to enhance the suitability of the guide wire for use within catheters and vascular lumen.” However, this teaching is not, in fact, found in Palermo. Palermo teaches that a thin layer of a hydrophilic polymer can be applied to enhance lubricity of the guidewire core. However, PEBA<sup>X</sup> is disclosed to be useful only for the proximal portion of the guidewire. Palermo makes a distinction between coatings for use on the proximal and distal portions of the guidewire, and thus teaches away from the claimed invention, which requires (per dependency on claim 8) that the core wire be “substantially completely covered with a second polymeric material.” Thus, the covering of the claimed invention is distinguishable from that disclosed in Palermo.

Based on at least these important distinctions, one of skill in the art armed with the teachings of the cited references, would not be motivated to arrive at the instant invention. Therefore, withdrawal of the rejection is respectfully requested.

### Summary

In summary, each of claims, as amended, are in condition for allowance. Reconsideration of the Office Action is respectfully requested. Further and favorable action in the form of a Notice of Allowance is earnestly solicited. The Examiner is invited to contact Applicant’s undersigned representative at the telephone number listed below, if it is believed that doing so will expedite prosecution of this patent application.

Respectfully submitted

  
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

The paragraph beginning at page 4, line 18 was amended as follows:

--A preferred class of materials, which is non-metallic in accordance with this invention, comprises polymeric materials. Polymeric materials useable in the present invention are preferably hydrocarbon-based comprised of the elements of carbon and hydrogen. However, hydrocarbon polymer [is] useable in the present invention can, and often will, include oxygen, nitrogen, or other elements, usually as minor constituents.—

The paragraph beginning at page 7, line 4 was amended as follows:

--Guide wire body 11 is non-metallic, and in a preferred practice, polymeric. The overall diameter of the guide wire of at least the medial segment shown in FIG. 1 (at arrows 15) is approximately 0.035 inches. A preferred polymeric material for guide wire body 11 is polyetheretherketone, sold under the designation PEEK. PEEK as is used in accordance with this invention is commercially available from many sources. A preferred source is Zeus Industrial Products, Inc. in Orangeburg, South Carolina, U.S.A. [<HTTP://www.zeusinc.com>]). PEEK is preferred for use in the present invention because it is camber resistant, having little tendency to break when sharply bent. It is also thermally stable permitting other polymeric materials to be extruded over it without change in dimension. PEEK is also believed to be capable of being impregnated with glass fibers, *e.g.*, to alter its handling characteristics. "Camber resistant" herein means having the property or tendency not to become curved when held in a circular package while being shipped. Camber resistance could also be described as not having the tendency to remain curved or circular even though guide wires are commercially shipped in circular carriers. The absence of camber means that medical personnel using a device of this invention can remove it from its generally circular shipping tube (the device may have been maintained in a circular configuration for several months while the device was in inventory and being shipped) and still be immediately useable, *e.g.*, for catheter placement.—

The paragraph beginning at page 10, line 14 was amended as follows:

--FIG. 4 illustrates a variation of the structure shown in FIG. 3 in which a polymer-based jacket material 70 is disposed on the distal segment 72 of guide wire core wire 74. An optional adhesive 76 may be used to adhere jacket material 70 to core wire 74. Illustrative polymeric jacket materials include, polyurethane and [Pebax] PEBAX as is described above.—

On page 15, the Abstract was amended as follows:

--A guide wire having a non-metallic, non-woven core wire is disclosed. Monofilar, polymeric fibers [of] or multifilar helically-wound non-metallic fibers are preferred core wire materials. The guide wire optionally includes further coatings and other materials on the core wire. In one embodiment, a non-metallic distal coil wire is disclosed. The guide wire of this invention is particularly useable for magnetic resonance imaging applications.—

Claims 1, 4, 5, 8, 14, 18 and 22 were amended as follows:

4. (AMENDED) A guide wire according to claim 1 wherein the core wire has a polymeric coating thereon which covers substantially the entire length of the [guide] core wire.

5. (AMENDED) A guide wire according to claim 1 wherein core wire has a tapered segment between the [medal] medial segment and the distal segment.

14. (AMENDED) A guide wire according to claim [10] 8 wherein the core wire is coated with PEBA<sup>X</sup> polyetherimide.

15. (AMENDED) A guide wire according to claim [10] 8 wherein the core wire comprises polyetheretherketone, and the core wire is coated with polyetherimide.

18. (AMENDED) A guide wire according to claim [10] 15 wherein the polyetherimide coating has a hydrophilic coating thereover.

19. (AMENDED) A guide wire comprising a core wire having coupled distal, medial, and proximal segments, the core wire comprising multiple, [helically-wound] non-metallic, randomly-disposed fibers and a binder resin, the binder resin being uniformly dispersed between the fibers so as to fill any void space therebetween.